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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,582	12/19/2000	Man C. Niu	13402.00004	6349

7590 01/15/2003

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,582

Applicant(s)

NIU, MAN C

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2002 and 01 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-22 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-16, 19-22, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 15
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-16, 19-22, and 25-27 are pending.

The amendments filed 10/1/02 and 10/10/02 have been entered.

Claims 17, 18, 23, and 24 have been canceled.

Claims 26 and 27 have been added.

Claims 1-16, 19-22 and 25-27 are examined in the present Office Action.
2. Rejections and objections not set forth below are withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Objections

4. Claim 27 is objected to for being a duplicate of claim 26.
5. Claims 1-15, 19-20, 22, and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/21/2002. Applicant's arguments have been fully considered but they are not persuasive.

The Applicant reiterates that methods for preventing RNA degradation are well known to those of skill in the art and in regards to the mechanism concerning mRNA transfer to the nucleus, Applicant contends that "an inventor need not know the why of the scientific and

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technologic principles underlying an invention” (sentence bridging page 9-10). Applicant asserts that the data presented in Figure 6 clearly shows the incorporation of Soy DNA into the genome of the transgenic corn plant (page 10, middle paragraph).

The Examiner agrees with the Applicant on all points discussed above. Based on the information Applicant has provided in the specification, Applicant is enabled for isolating mRNA from soy cotyledons or sprouts (page 13, lines 4-8), transforming corn kernels of corn varieties 27-1 and 85089 using the microinjection technique disclosed in the specification (page 13, lines 8-17) and is enabled for claims drawn to transgenic corn plants and kernels of corn strain 27-1 and 85089 expressing soy globulin protein. Applicant is not enabled for isolating and purifying soy globulin mRNA from soy sprouts or cotyledons as this procedure is not disclosed at all in the specification. One of skill in the art would need guidance or examples as to how one identifies soy globulin mRNA from all the RNA species that would be isolated during a routine mRNA preparation. No information is given as to the size of the mRNA molecule or where on a gel one would expect to find the specific mRNA molecule. Given the inherent problems of working with RNA in regards to the ubiquitous nature of RNases, attempting to cut out a band of interest from a gel is highly problematic and not routinely done. Applicant is also not enabled for a method for producing any transgenic plant which expresses any exogenous protein. Given the arguments presented in the previous office action, Applicant is only enabled for a method of expressing soy globulin protein in corn strains 27-1 and 85089 given the method as described in the specification.

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6. Claims 11-16, 19-22, and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the corn strains 27-1 and 85089 claimed are essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If corn strains 27-1 and 85089 are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same corn strains 27-1 and 85089 in each occurrence and it is not apparent if such a corn strain is readily available to the public. If the deposit of these corn strains is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the corn varieties will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

7. Claim 8, 13, 14, 15, 22, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 8, 13, 14, 15, 22, and 25, the metes and bounds of “sprouts” has not been defined. Applicant has not specified the age of the sprouts or the size. One skilled in the art would not know at what stage of plant development to isolate mRNA given that the RNA profile of an organism changes as the organism develops.

8. Claims 1-16, 19-22, and 25-26 are rejected.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

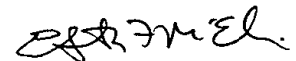
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organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Tiffiany Tabb, whose telephone number is (703) 605-1238.

Stuart F. Baum Ph.D.

January 13, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600